

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**QUESTIONABLE MEDICARE PAYMENTS
FOR WOUND CARE SUPPLIES**



JUNE GIBBS BROWN
Inspector General

OCTOBER 1995
03-94-00790

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EXECUTIVE SUMMARY

PURPOSE

This report identifies questionable billing practices for wound care supplies under Medicare Part B.

BACKGROUND

Wound care supplies are protective covers or fillers that treat openings on the body caused by surgical procedures, wounds, ulcers, or burns. The Health Care Financing Administration (HCFA) reimburses for wound care supplies under Medicare Part A through its payments to nursing homes and home health agencies and Medicare Part B through its payments to suppliers. The HCFA broadened its coverage policy on March 30, 1994, allowing payment for secondary as well as primary dressings and including wound treatments by non-physicians.

The HCFA contracted four DME Regional Carriers (DMERCs) starting October 1993 to process wound care supply claims. In June 1994, reimbursements for these supplies were based on a fee schedule and the number of wound care supply codes increased from less than 20 to over 60. The DMERCs revised their guidelines and requested comments in January 1995. These guidelines clarify utilization and medical necessity issues. The effective date for implementing the revised guidelines is October 1, 1995.

This inspection was conducted as part of Operation Restore Trust, a pilot program that coordinates Federal, State, and local anti-fraud activity in California, Florida, New York, Illinois, and Texas. The program will target abuses in home health agencies, nursing facilities, and durable medical equipment, including wound care supplies.

We selected claims for a 1 percent sample of beneficiaries who received wound care supplies between June 1994, the start of fee schedule reimbursements, and February 1995. We applied the proposed DMERC draft guidelines to these claims to identify questionable billing practices. Lastly, we quantified the potential impact of questionable billing practices and identified potentially abusive suppliers.

FINDINGS

Questionable payments of wound care supplies may account for as much as two-thirds of the \$98 million in Medicare allowances from June 1994 through February 1995.

Four supplies, hydrogel wound filler, tape, a hydrogel dressing wound cover, and a foam dressing wound cover, account for almost half of the excessive utilization. We found excessive utilization in all groups of wound care products. The DMERC D found similar abuses in its detailed review of wound care claims.

Activity is concentrated in States, suppliers, place of service, and one carrier.

Almost two-thirds of excessive wound care payments was found in eight States. These States are Puerto Rico, Indiana, New York, California, Illinois, Tennessee, Florida, and Louisiana. The five Operation Restore Trust States account for over one-third of the questioned amounts. Three-quarters of excessive payments in our sample were made to 48 suppliers which represent 7 percent of the suppliers in our sample. Less than 40 percent of beneficiaries resided in skilled nursing or nursing facilities but these beneficiaries received over 70 percent of wound care benefits. The DMERC C allowed almost twice the national average per beneficiary and was responsible for over 40 percent of questionable wound care payments.

The HCFA and DMERCs have taken corrective actions to address wound care abuses and continue to explore others.

The DMERCs, working with the HCFA, published a draft policy to clarify wound care coverage to take effect October 1, 1995. They have also identified suppliers responsible for questionable billing practices, some of which use multiple identification numbers. This has resulted in both sanctions and continuing education for suppliers. However, DMERC officials believe there are insufficient resources to conduct the necessary program integrity activities. They also expressed frustration in National Supplier Clearinghouse's inability to prevent abusive suppliers from obtaining provider identification numbers. The HCFA is also considering "bundling" ancillary products such as wound care supplies into the reimbursement for nursing homes.

RECOMMENDATION

A long term solution would require HCFA to bundle services in their Medicare or Medicaid payments to nursing homes. For example, the nursing home patients that received wound care supplies would not be separately reimbursed for these supplies but have them included in the per diem rate paid by Medicare or Medicaid. We continue to support HCFA's efforts to pursue a bundling policy. To address the immediate problems with wound care supplies identified in this report, we recommend that:

- ▶ HCFA should target their limited program integrity resources to those areas identified as most vulnerable to abuse. This could include edit screens at each DMERCs to track such wound care products as tape and hydrogel.
- ▶ HCFA should continue to monitor wound care activity through 1996 to determine if the level of questionable payments continues. If questioned payments continue unabated, HCFA may need to reconsider the current wound care benefit.

COMMENTS

We solicited and received comments on our draft reports from HCFA and other concerned organizations. The organizations that provided us with responses were the Health Industry Distributors Association (HIDA), the Health Industry Manufacturers Association (HIMA), and the National Association for the Support of Long Term Care (NASL). The full text of their comments is provided in Appendix C.

The HCFA agreed with the recommendations. In addition, HCFA responded that they have developed a legislative proposal to require bundling of services, including wound care supplies, in Medicare and Medicaid payments to nursing homes. They believe that this may serve as an incentive for nursing homes to more closely monitor the use of wound care supplies.

The outside organizations commented that they strongly support HCFA's expansion of the national coverage policy for wound care supplies and that no reduction in the current scope of the benefit should be considered. They believe that the DMERCs' delay in implementing wound care policies and utilization standards after HCFA's expansion of the policy was the primary factor in creating an environment ripe for potential abusive practices.

The outside groups believe there are significant flaws in the methodology we used to determine the magnitude of questionable billing of wound care supplies. The primary weakness, they believe, is the "unfair" application of DMERC guidelines to claims that were not affected by these guidelines.

While we believe the initial lack of DMERC policies without utilization standards for wound care supplies played a part in allowing abuses to occur, we do not believe it to be the entire cause of abusive supplier practices. Even without specific utilization standards, suppliers are supposed to be able to support the medical necessity of the wound care products they deliver. Some of the examples of questionable billings that we encountered were not mere misunderstandings of medical policies for wound care. For example, when suppliers are billing amounts large enough to purchase 12.5 miles of tape or 5 gallons of hydrogel wound filler in a 6-month period this would fall out of even the most generous clinical guidelines.

We believe our methodology was sound and consistent with prior OIG efforts to identify claims that appear questionable. In response to the organizations' concern that we used the DMERCs' proposed guidelines for our review, we used these policies because we felt the utilization standards they contained would provide us with information on the scope and nature of the problems with wound care supply claims. The supply industry had participated in the development of these guidelines and were generally supportive of them. Furthermore, there were no other non-trade association guidelines available for wound care supply utilization that were as extensive as the

proposed DMERC policies. Finally, we thought this information would be useful to HCFA and the DMERCs in preparing for the implementation of the policy guidelines.

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INTRODUCTION

PURPOSE

This report identifies questionable billing practices for wound care supplies under Medicare Part B.

BACKGROUND

Wound care supplies are fillers or protective covers that treat openings on the body caused by surgical procedures, wounds, ulcers, or burns. Wound covers are flat dressing pads. Wound fillers are dressings placed into open wounds to eliminate dead space, absorb exudate, or maintain a moist wound surface. The Health Care Financing Administration (HCFA) reimburses for wound care supplies under the Medicare Part B program. Wound care coverage policy is found in section 2079 of the Medicare Carriers Manual. The HCFA contracts four DME regional carriers (DMERCs) to process durable medical equipment claims including wound care supplies. The DMERCs issue their own guidelines to clarify their coverage policy.

Medicare Part B Allowances for Wound Care Supplies: 1990 - 1994

There were significant changes in wound care activity between 1990 and 1994. Medicare Part B allowances were as low as \$50 million in 1992 and peaked in 1993 at \$132 million, an increase of 164 percent. The number of beneficiaries that annually received these supplies ranged from 86,600 in 1993 to as high as 273,300 in 1991. As a result, allowances per beneficiary varied from \$199 in 1990 to \$1,526 in 1993. Between 1993 and 1994 the number of Medicare beneficiaries that received wound care supplies increased 47 percent.

In 1994, 61 percent of the average allowance per beneficiary was for specialty dressings. Medicare fee schedule amounts for specialty dressings are as high as \$35 for large hydrogel wound covers. Eleven of the specialty wound care products are reimbursed by Medicare at over \$10. Prior to 1992, Medicare reimbursed for wound care supplies primarily in a single kit payment. These kits were a compilation of wound care supplies and were reimbursed at \$8 each in 1992. Billing for kits was disallowed in 1992. However, component supplies contained in a kit can still be billed as individual products. As a result, the number of wound care supplies has increased over six times from 13 million in 1991 to 81 million in 1994. The table on the following page summarizes surgical dressing activity for calendar years 1990 through 1994.

Table 1. Wound Care Supply Activity: 1990 - 1994

Activity	1990	1991	1992	1993	1994
Allowances	\$53 million	\$87 million	\$50 million	\$132 million	\$98 million
Beneficiaries	266,400	273,300	117,300	86,600	127,300
Per Beneficiary	\$199	\$317	\$423	\$1,526	\$769
No. of Supplies	N/A	13 million	45 million	69 million	81 million

The HCFA Broadens its Coverage Policy for Wound Care Supplies

On March 30, 1994, HCFA expanded its coverage policy for wound care supplies. The new policy provides coverage for "primary and secondary dressings required for the treatment of a wound caused by, or treated by, a surgical procedure that has been performed by a physician or other health care professional." Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. These include alginate, foam, specialty absorptive, hydrogel, hydrocolloid, and composite dressings. Transparent film and contact layers also serve as primary dressings. Secondary dressings serve a therapeutic or protective function and typically are needed to secure a primary dressing. Items such as adhesive tape, roll gauze, and bandages are examples of secondary dressings.

The Prior Coverage Policy Was More Restrictive

The HCFA national policy and the DMERCs' policies prior to March 30, 1994 were more restrictive. Stringent requirements were placed on the type of dressings, length of treatment, cause of wound, type of provider, and medical documentation. The DMERCs' policy before the expansion of the national policy covered only primary dressings resulting from a surgical procedure for usually no more than 2 weeks. This policy stated that "surgical dressings for closed incisions without drainage would rarely be medically necessary for more than 1 week" and "when an ulcer, traumatic wound, or burn has had sharp debridement, it will be considered a surgical wound for no more than 2 weeks from the date of debridement."

Prior to March 30, 1994, the HCFA national policy would allow dressings to be covered for treatment of wounds that resulted from sharp debridement (e.g., scalpel, laser) performed **only** by physician. The DMERC local policies stated that dressings for other types of debridement (e.g., mechanical, chemical, autolytic) were not covered. Wound care suppliers were required by DMERCs to submit a certificate of medical necessity to document the need for the products. After the policy change in March 1994, this was no longer required. The table on the following page compares the wound care supply policy before and after March 30, 1994.

Table 2. Comparison of Wound Care Supply Coverage Policies

Wound Care Supply Coverage Policy Prior to March 30, 1994	Wound Care Supply Coverage Policy Effective March 30, 1994
Only primary dressings	Primary and secondary dressings
Time limits on medical necessity	As long as medically necessary
Dressings for sharp debridement only	Any type of debridement
Limited to physician treatments	Physician and non-physician treatments
Certificate of Medical Necessity required	Certificate of Medical Necessity not required

Carrier Processing of Wound Care Supplies

In June 1992, HCFA issued a final rule designating four Durable Medical Equipment Regional Carriers (DMERCs) to process all claims for durable medical equipment, including wound care supplies. The four carriers are the MetraHealth Insurance Company (DMERC A), AdminaStar Federal (DMERC B), Palmetto Government Benefits Administrators (DMERC C) and Cigna Healthcare (DMERC D). Effective October 1, 1993, HCFA began the transition to the DMERC processing of wound care supply claims. During 1994, 56 carriers also processed surgical dressing claims before the transition to DMERCs was complete. During the transition, these carriers did not utilize the DMERC policies; they carriers used their own local policies to process claims.

The DMERCs Implement a Fee Schedule and Introduce New Codes

Starting in June 1994, reimbursements for wound care supplies were based on a fee schedule. The DMERCs introduced over 60 codes for wound care products to implement the fee schedule. Prior to June, less than 20 codes were used to identify and reimburse dressings. The DMERCs granted a grace period for all but two old codes submitted through October 1, 1994. During the grace period the DMERC would crosswalk the old code to the appropriate new code.

The DMERCs Issue a Draft Policy to Clarify Wound Care Coverage

The DMERCs, working with HCFA, developed a policy to clarify the coverage of the wound care benefit. In January 1995, each DMERC requested comments on these guidelines. Included in these guidelines are definitive utilization and medical necessity parameters. In addition, modifiers to the codes have been added to identify the number of wound sites being treated. The HCFA and DMERCs have evaluated the comments and have issued a revised policy to be effective October 1, 1995. See Appendix A for a summary of the utilization guidelines.

This change was initiated in part as a response to organizations in the wound care community that expressed the need for clarification. For example, the Health Industry Distributors Association in cooperation with the National Coalition for Wound Care, the National Association of Retail Druggists, and the National Association for the Support of Long Term Care developed consensus recommendations for improving the Medicare wound care policy. These changes were recommended prior to the release of the proposed changes in January 1995.

The General Accounting Office Discloses Similar Abuses

The General Accounting Office (GAO) issued a final report, *Medicare: Excessive Payments for Medical Supplies Continue Despite Improvements (HEHS-95-171)*, in August 1995 concerning payment controls for Medicare expenditures of durable medical equipment with an emphasis on wound care supplies. The GAO found a "lack of system wide controls" which led to abuse in both Part A and Part B. For example, the number of dressings billed per beneficiary was nearly three times higher under 29 new wound care codes. They attribute this to the absence of a clearly defined policy.

Operation Restore Trust Targets Health Care Abuse in Five States

Operation Restore Trust is a health care anti-fraud demonstration project developed within the U.S. Department of Health and Human Services by the Office of Inspector General, the Health Care Financing Administration, and the Administration on Aging. Its aim is to coordinate Federal and State resources to attack fraud and abuse in home health agencies, nursing facilities, and durable medical equipment, including wound care supplies. The project's initial focus will be in California, Florida, New York, Illinois, and Texas.

METHODOLOGY

To assess the nature of questionable billing practices, we interviewed DMERC officials including medical directors and fraud control personnel. Each DMERC responded to a questionnaire concerning wound care supply processing guidelines, the nature of questionable billing practices, and corrective actions taken.

To determine the extent of questionable billing practices, we analyzed a 1 percent sample of wound care beneficiaries. These beneficiaries received supplies under one of 87 wound care supply codes in use between June 1994, the start of fee schedule reimbursements, through February 1995. These claims are maintained in HCFA's National Claims History 100 percent Physician/Supplier database. Medicare Part B allowed \$980,270 in wound care supplies for our sample of 1,205 beneficiaries for this 9-month period. Allowed payments include the 80 percent Medicare payment and the 20 percent coinsurance fee billed to the beneficiary.

We applied the proposed DMERC draft guidelines to these claims to identify questionable billing practices. Although these guidelines were not in force during the review period, they represent a consensus concerning wound care policy that could be systematically applied and measured. We assumed the maximum allowable usage each month for the month in which the supply was billed. We defined a questionable billing practice as that amount in excess of the utilization guideline. We assumed each type of wound cover billed represented a wound site. We reported Medicare allowances above the tolerance levels by type of supply, DMERC, number of beneficiaries receiving supplies, and supplier. To determine if a link exists among suppliers suspected of abusive billing practices, we reviewed data from the National Supplier Clearinghouse (NSC). Under each provider identification number, the NSC database includes the name of corporate officials, addresses, and provider aliases.

Claims for tape supplies (HCPCS A4454 and K0265) were analyzed differently. We selected 101 beneficiaries from two groups of a stratified sample of 349 beneficiaries that received tape. The first strata contained 31 beneficiaries that received \$1,000 or more in tape. The second, 318 beneficiaries that received between \$25 and \$999 in tape. We selected all 31 from the first strata and randomly selected 70 beneficiaries from the second. This sample of 101 beneficiaries represent \$73,848.13 or 52 percent of total allowed dollars in tape claims. For each tape claim, we assumed that the beneficiary used the maximum monthly allowable usage for each primary and secondary dressing billed during that month according to the proposed DMERC draft guidelines. The secondary dressing was allocated the same amount of tape as the primary dressing. Dressings with an adhesive border were not allocated tape.

We assumed dressings less than or equal to 16 square inches to be 4 inch by 4 inch. We assumed a 6 inch by 8 inch size for dressing between 16 and 48 square inches and 8 inches by 8 inches for dressings greater than or equal to 48 square inches. We allocated two inches extra of tape for each side. Therefore, a 4 inch by 4 inch dressing was allocated 24 inches of 1 inch tape. A 6 inch by 8 inch dressing was allocated 36 inches and a 8 inch by 8 inch dressing, 40 inches. We applied the current fee schedule price of \$0.12 per 18 square inches to the tape allocated. Each 4 inch by 4 inch dressing used \$0.16 in tape. A 6 inch by 8 inch dressing used \$0.24 in tape, \$0.27 for a 8 inch by 8 inch dressing. To quantify the impact of questionable billing practices, we projected our findings, by multiplying Medicare allowances above the proposed DMERC guidelines by 100. Confidence intervals for our projections are presented in Appendix B.

We compared the results of this analysis with data supplied by DMERC D. In January 1995, DMERC D required 30 suppliers that had been placed on prepayment review to submit documentation to support future claims. The DMERC D, with assistance from nurses in the Wound, Ostomy and Continence Nurses Society, reviewed 687 claims for 525 beneficiaries from 14 suppliers that continued to submit wound care claims. The 687 claims averaged \$433, \$302 of which was for hydrogel and foam dressings. Almost 60 percent of the wound care supplies billed were for gauze. However, the allowances for these gauze products represent only 7 percent of

all wound care allowances reviewed. The nurses reviewed these documents to determine the actual type and number of wound care supplies needed for effective treatment. We applied the DMERC D fee schedule prices to the units billed and the units allowed to quantify the effect of their adjustments. We used June 1994 through February 1995 data to provide unit costs when prices were unavailable in the DMERC D fee schedule.

Report Presentation

This report is one of three reports concerning Medicare payments for wound care supplies. The second report, *Marketing of Wound Care Supplies (OEI-03-94-00791)* describes supplier and nursing home practices that can lead to questionable payments and examines issues concerning Medicare beneficiaries' use of wound care supplies. The third report, *Wound Care Supplies: Operation Restore Trust Data (OEI-03-94-00792)*, consolidates information presented in the other two wound care reports as it pertain to the five Operation Restore Trust States.

This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency and is part of Operation Restore Trust.

FINDINGS

QUESTIONABLE PAYMENTS FOR WOUND CARE SUPPLIES MAY ACCOUNT FOR AS MUCH AS TWO-THIRDS OF THE \$98 MILLION IN MEDICARE ALLOWANCES FROM JUNE 1994 THROUGH FEBRUARY 1995.

Medicare Part B allowed \$65 million from June 1994 through February 1995 for 46 million wound care supplies that exceed the proposed DMERC guidelines. This represents 66 percent of \$98 million in Medicare Part B allowances and 57 percent of the 81 million wound care supplies provided to beneficiaries.

Excessive utilization evident in all wound care products.

Each group of wound care products showed a significant degree of questionable billing. Transparent film led with 80 percent of its activity that exceeded utilization guidelines. The group with the smallest level, alginate dressings, had 40 percent of the Medicare allowance and 50 percent of the units that exceed utilization guidelines. The table below summarizes the excessive allowances and units for each group of wound care product. The total figures are the amounts that exceeded utilization guidelines. The percentages represent the portion of the total billings for that group over the standard.

Table 3. Excessive Allowances and Units by Wound Care Product

Wound Care Product	Exceeded Utilization Guidelines			
	Allowance	%	Units	%
Hydrogel Dressings	\$24.8 million	77%	2.4 million	74%
Tape	\$9.8 million	68%	5.1 million	68%
Gauze	\$7.8 million	49%	33.0 million	53%
Foam Dressings	\$7.4 million	70%	0.9 million	68%
Specialty Absorptive Dressings	\$4.0 million	62%	1.8 million	63%
Alginate Dressings	\$2.9 million	40%	0.5 million	50%
Other Supplies	\$2.8 million	77%	0.7 million	82%
Transparent Film	\$2.3 million	80%	0.8 million	80%
Hydrocolloid Dressings	\$2.0 million	54%	0.6 million	65%
Composite Dressings	\$0.7 million	71%	0.2 million	69%
Contact Layer	\$0.0 million	N/A	0.0 million	N/A
Total - Wound Care Supplies	\$64.5 million	66%	46.0 million	57%

Four supplies account for almost half of the questionable Medicare allowances.

Medicare allowances for hydrogel wound filler, tape, a hydrogel dressing wound cover, and a foam dressing wound cover that exceeded utilization guidelines totaled \$31 million. These supplies represent 48 percent of excess allowances but only 15 percent of the 46 million units that were overbilled. The wide range of prices for wound care supplies cause this concentration. Medicare allowed an average of \$10 for each hydrogel dressing supply, while gauze products averaged 26 cents each.

A further analysis of tape and hydrogel wound filler illustrates the magnitude of these questionable billings. From June 1994 through February 1995, \$10 million of Medicare's \$14 million allowance for tape appears questionable. For 95 percent of beneficiaries in the sample, some portion of their tape expenditures was questioned. One-quarter of these beneficiaries had at least \$1,000 in tape questioned. Applying tape to 90 4" x 4" pads per month, it would take 5 years to consume \$1,000.

One beneficiary was charged with \$5,290 in tape over a 6-month period, almost \$5,000 of which appears excessive. Medicare paid for, but probably did not receive, 66,000 feet or 12.5 miles of one-inch tape. This beneficiary needed only \$324 or 2,700 feet in tape if all the dressings purchased were used to the maximum allowed. This beneficiary would need to use over 33,000 4" x 4" gauze pads to use this much tape, a 30 year supply at 90 pads per month.

Another beneficiary was charged with \$11,880 in hydrogel wound filler, \$11,533 of which may be unnecessary. This beneficiary's record showed payments for 120 units of one-ounce hydrogel wound filler each month for 6 consecutive months, over 5 gallons. The proposed guidelines call for three per month or three ounces per wound site, which should have cost Medicare \$347. The guidelines state that "hydrogel filler used for each wound should not exceed the amount needed to line the surface of the wound," not fill the wound cavity.

The DMERC D finds similar abuses in its review of wound care claims.

The findings from the DMERC D review of 687 wound care claims submitted by suppliers on pre-payment review mirrors the abuses nationwide. The DMERC D disallowed 61 percent of the 112,000 wound care supplies in its review. As a result, 54 percent of the almost \$300,000 in wound care claims were questioned. Tape accounted for only 5 percent of the charges reviewed by the DMERC as opposed to 15 percent nationally. However, the DMERC also questioned almost two-thirds of all tape. The table on the following page presents the percentage of the charges and units submitted for each group of wound care products that were not allowed by DMERC D.

Table 4. Summary of DMERC D Review of Wound Care Claims

Wound Care Product	Disallowance Rate	
	Charges Submitted	Units Submitted
Alginate Dressings	37%	42%
Composite Dressings	56%	56%
Foam Dressings	52%	49%
Gauze	65%	67%
Hydrocolloid Dressings	46%	46%
Hydrogel Dressings	54%	52%
Specialty Absorptive Dressings	30%	32%
Tape	63%	63%
Transparent Film	52%	51%
Other Supplies	69%	64%
Total - Wound Care Supplies	54%	61%

ACTIVITY IS CONCENTRATED IN STATES, SUPPLIERS, PLACE OF SERVICE, AND ONE CARRIER.

Almost two-thirds of excessive wound care payments was found in eight States.

Eight States account for \$42 million or 65 percent of the Medicare allowances that exceeded the DMERC guidelines. Two States with relatively small Medicare populations, Puerto Rico and Indiana were included in this group. The other six States are New York, California, Illinois, Tennessee, Florida, and Louisiana. These eight States were also responsible for \$62 million or 63 percent of the total Medicare allowances.

The five Operation Restore Trust States account for over one-third percent of the questioned allowances.

The five States targeted by Operation Restore Trust accounted for 35 percent or \$22 million of Medicare allowances for wound care supplies that exceeded utilization guidelines. Non-tape accounted for over \$18 million of the questioned payments, tape approached \$4 million. Four of these States, New York, California, Illinois and Florida ranked in the top seven. The fifth State, Texas, received \$1.3 million in excessive payments. These States had 39,200 beneficiaries that received wound care supplies. Over 25,000 of these beneficiaries showed some excess utilization.

Three-quarters of excessive payments in our sample were made to 48 suppliers which represent 7 percent of the suppliers in our sample.

Out of the \$980,270 in wound care claims in our sample, we found \$546,665 in questionable non-tape payments. These amounts represent actual claims before projections were applied. Three-quarters of these excessive payments for non-tape wound care products were paid to 46 suppliers. The excessive Medicare payments to these suppliers ranged from \$2,752 to \$91,784. Two other suppliers that received at least \$2,752 in excessive tape payments were not in this group of 46. This total of 48 represents 7 percent of all suppliers in our sample. Fifty-seven percent of the suppliers in our sample (402 of 699) received some payments for supplies that exceeded utilization guidelines. One supplier received 17 percent of all excessive payments for non-tape supplies and 14 percent for tape. This supplier received more than four times the questionable non-tape payments than the next supplier, and almost 50 percent more for tape.

From June 1994 through February 1995, 71 percent of all Medicare payments for wound care supplies were made to 48 suppliers or 7 percent of all suppliers in our sample. These 48 suppliers each received payments of at least \$5,000. Conversely, more than 56 percent of suppliers received payments of \$100 or less and in total these account for less than 1 percent of all allowances. Forty-one of the 48 suppliers were those previously identified as receiving a high concentration of excessive payments.

Less than 40 percent of beneficiaries resided in Skilled Nursing or Nursing Facilities but these beneficiaries received over 70 percent of wound care benefits.

Almost 72 percent of Medicare allowed payments for wound care supplies in our sample was made for beneficiaries that resided in skilled nursing (SNF) or nursing facilities (NF). This same percentage also applies for beneficiaries in SNFs and NFs that received non-tape supplies that exceeded utilization guidelines. Only 38 percent of the beneficiaries in our sample resided in SNFs and NFs. Almost 52 percent of the beneficiaries lived at home. However, beneficiaries that received excessive non-tape supplies was almost equally divided between residents of SNFs and NFs and homes.

The DMERC C allowed almost twice the national average per beneficiary and was responsible for over 40 percent of questionable wound care payments.

The DMERC C allowed charge per beneficiary for wound care supplies was \$1,385, or almost twice the national average. The allowed charge per beneficiary ranged from \$606 to \$832 at the other DMERCs. The DMERC C made over \$41 million or 40 percent of all payments for wound care from June 1994 through February 1995. This was almost twice what was paid by DMERC A and DMERC B, and four times that of DMERC D.

The pattern is similar for submitted charges. The \$81 million submitted to DMERC C was 36 percent higher than DMERC A and almost five times of what was submitted

to DMERC D. For each beneficiary, suppliers submitted charges of \$2,192 to DMERC C, twice the national average. The table below summarizes wound care payments by carrier from our sample. The first group contains the total dollars, number of beneficiaries, and charge per beneficiary submitted to each carrier in our sample. The second group contains the allowed amounts for each carrier. Some beneficiaries received supplies through more than one carrier.

Table 5. Total Wound Care Supply Payments Per Carrier

Carrier	June 1994 - February 1995					
	Submitted Charges			Allowed Charges		
	Total Dollars	Bene-ficiaries	Per Bene-ficiary	Total Dollars	Bene-ficiaries	Per Bene-ficiary
DMERC A	\$59,317,300	43,800	\$1,354	\$21,385,200	35,300	\$606
DMERC B	\$48,766,300	33,400	\$1,460	\$21,983,500	26,400	\$832
DMERC C	\$80,658,200	36,800	\$2,192	\$41,420,600	29,900	\$1,385
DMERC D	\$16,415,700	23,800	\$689	\$10,493,400	16,700	\$628
Other	\$29,876,600	86,600	\$345	\$2,744,400	15,000	\$183
Total	\$235,034,100	224,400	\$1,047	\$98,027,100	123,300	\$795

The DMERC C made 44 percent of the non-tape payments and 49 percent of tape payments that exceeded utilization guidelines. The DMERC C paid for 29 percent of the beneficiaries that received excessive non-tape supplies, 43 percent for tape. The table below summarizes the non-tape and tape payments that exceeded utilization guidelines by each carrier.

Table 6. Excessive Wound Care Supply Payments Per Carrier

Carrier	Allowances That Exceeded Utilization Guidelines					
	Non-Tape Supplies	% of Total	Tape	% of Total	Total Supplies	% of Total
DMERC A	\$9,933,753	18%	\$1,960,304	20%	\$11,894,057	18%
DMERC B	\$13,228,005	24%	\$2,402,453	25%	\$15,630,458	24%
DMERC C	\$24,242,717	44%	\$4,618,661	47%	\$28,861,378	45%
DMERC D	\$5,554,847	10%	\$713,710	7%	\$6,268,557	10%
Other	\$1,707,097	3%	\$97,072	1%	\$1,804,169	3%
Total	\$54,666,419	100%	\$9,792,200	100%	\$64,458,619	100%

These payments almost double what was paid by DMERC B which was responsible for approximately one-quarter of excessive payments. The DMERC A made 18 percent on non-tape and 20 percent of tape payments that were questioned. Only 2 percent of non-tape and 5 percent of tape payments that exceeded DMERC guidelines were made by DMERC D.

THE HCFA AND DMERCs HAVE TAKEN CORRECTIVE ACTIONS TO ADDRESS WOUND CARE ABUSES AND CONTINUE TO EXPLORE OTHERS.

Revised wound care policy to clarify coverage guidelines

The most significant action taken by the HCFA to address abuses in wound care was the publication of revised a coverage policy. This policy developed along with the DMERCs, provides specific utilization and medical necessity standards that should clarify acceptable clinical practices.

The DMERCs identified 54 abusive suppliers, some of which are the same companies using different provider identification numbers.

Through pre- and postpayment reviews, the DMERCs have identified 54 suppliers suspected of questionable billing practices. The DMERC D identified 30 of these suppliers; DMERC C, 17, DMERC B, 10, and DMERC A, 7. Seven suppliers were identified by more than one DMERC. The 54 suppliers include 21 identified in this report. The DMERCs require these suppliers to document future claims. The DMERCs also referred suppliers to the Office of Inspector General for investigation or suspended their payments. The DMERC A has even dedicated a portion of the medical review staff to wound care. However, DMERC officials believe they do not have the resources necessary to perform the proper level of review needed to assure sufficient control. In certain situations, questionable billing was attributed to a misunderstanding of wound care policy. In these cases, DMERCs provide the necessary education to clarify the acceptable guidelines.

In total, 81 suppliers were identified as being suspected of questionable billing practices. Of the these suppliers, 33 were identified by DMERCs, 21 by both the DMERCs and the Office of Inspector General (OIG), and 27 solely by the OIG. These 27 suppliers were part of the 48 suppliers identified as receiving three quarters of the excessive payments in our sample. Some of the suppliers had common identifying information linking them together. One group of three suppliers shared a common official. Another group of two suppliers also shared common officials. One group of four suppliers shared a common address. Another two suppliers shared a common address. The DMERCs expressed frustration in National Supply Clearinghouse's inability to prevent this abuse.

The HCFA is pursuing alternatives to the current cost reimbursement mechanism.

The HCFA continues to pursue a systematic solution to the abuses presented in this and other reports through a requirement for "bundling" of services in nursing home settings. Under such an approach, the nursing home would be responsible for providing commonly needed services to residents of that facility, rather than allowing for separate billing by suppliers. Such a solution would eliminate the incentives suppliers now have to aggressively seek out patients in nursing homes and market their products inappropriately in those settings. It would also ensure that nursing homes take on appropriate responsibilities for services and supplies delivered to residents in their facilities.

RECOMMENDATIONS

After Medicare's expansion of the wound care benefit in March 1994, it is not surprising that recent activity shows an increase in the number of beneficiaries. This coupled with the use of costlier specialty products have resulted in an increase in Medicare expenditures. In both January and February 1995 wound care activity was higher than in any month in 1994. With an increase in wound care activity and the level of abuse identified in this report, the need for stricter controls is evident. We believe the new guidelines should provide the framework for those controls. We also support ongoing activity in HCFA and the DMERCs to educate providers and suppliers about proper billing for such supplies. We hope the information contained in this report is helpful in their efforts.

A long term solution to wound care supply abuses would require HCFA to bundle services in their Medicare or Medicaid payments to nursing homes. For example, the nursing home patients that received wound care supplies would not be separately reimbursed for these supplies but have them included in the per diem rate paid by Medicare or Medicaid. We continue to support HCFA's efforts to pursue a bundling policy. We believe the level of abuse we found in skilled nursing and nursing facilities under Medicare Part B enhances this position.

To address the immediate problems with wound care supplies identified in this report, we recommend that:

- ▶ HCFA should target their limited program integrity resources to those areas identified as most vulnerable to abuse. This could include edit screens at each DMERCs to track such wound care products as tape and hydrogel.
- ▶ HCFA should continue to monitor wound care activity through 1996 to determine if the level of questionable payments continues. If questioned payments continue unabated, HCFA may need to reconsider the current wound care benefit.

AGENCY AND OUTSIDE ORGANIZATIONS' COMMENTS

We solicited and received comments on our draft reports from HCFA and other concerned organizations. The organizations that provided us with responses were the Health Industry Distributors Association (HIDA), the Health Industry Manufacturers Association (HIMA), and the National Association for the Support of Long Term Care (NASL). The complete text of their responses is included in Appendix C. A summary of the comments and our response follows.

HCFA Comments

The HCFA agreed with the recommendations. In addition, HCFA responded that they have developed a legislative proposal to require bundling of services, including wound care supplies, in Medicare and Medicaid payments to nursing homes. They believe that this may serve as an incentive for nursing homes to more closely monitor the use of wound care supplies. The HCFA also provided us with a technical comment concerning the need to emphasize the difference between national and regional coverage policies on wound care supplies.

Outside Organizations' Comments

The organizations commented that they strongly support HCFA's expansion of the national coverage policy for wound care supplies and that no reduction in the current scope of the benefit should be considered. They believe that the DMERCs' delay in implementing wound care policies and utilization standards after HCFA's expansion of the policy was the primary factor in creating an environment ripe for potential abusive practices. While the organizations support the need for implementing DMERC medical policies for wound care supplies that reflect current clinical practice, they also believe that some of the utilization standards in the DMERC policy to be implemented on October 1, 1995 are incorrect and need to be resolved before implementation occurs. The NASL and HIMA also stated that the DMERC policy prior to March 30, 1994 that we discuss in the background section of our report was never fully implemented.

All these groups believe there are significant flaws in the methodology we used to determine the magnitude of questionable billing of wound care supplies. The primary weakness, they believe, is the "unfair" application of DMERC guidelines to claims that were not affected by these guidelines. Secondly, the outside organizations feel the OIG's failure to determine the appropriateness of wound treatment on an individual basis does not allow for an effective analysis. For example, the number of wound covers applied to a patient with multiple wounds may exceed the DMERC guideline for a single wound cover. In addition, NASL cited that the OIG did not account for the nature of the dressing, i.e., primary or secondary, which also affects the frequency of changes. The NASL also believes that only the largest claims were targeted for review which skewed the findings.

The HIDA and HIMA believe that the new DMERC guidelines will have a positive effect in addressing any abuses in wound supplies that may exist. The HIDA wanted the OIG to highlight that most suppliers do not engage in questionable billing practice. The NASL and HIMA recommend a future review of wound supply activity to "ensure the proper integrity of the benefit." The HIDA recommends (1) the use of Certificates of Medical Necessity for abusive suppliers and overutilized items, (2) the establishment of a technical review committee representing suppliers, patients, and clinicians to work with HCFA and the DMERCs in analyzing claim activity, and (3) bundling most medical supplies into the nursing facilities Part A claim only for the first

100 days. Finally, HIMA believes HCFA and OIG should give the medical policy guidelines a chance to take effect before they reach any conclusion on the recommendation regarding bundling of wound care products.

OIG RESPONSE

While we believe the initial lack of DMERC policies without utilization standards for wound care supplies played a part in allowing abuses to occur, we do not believe it to be the entire cause of abusive supplier practices. Even without specific utilization standards, suppliers are supposed to be able to support the medical necessity of the wound care products they deliver. Some of the examples of questionable billings that we encountered were not mere misunderstandings of medical policies for wound care. For example, when suppliers are billing for amounts large enough to purchase 12.5 miles of tape or 5 gallons of hydrogel wound filler in a 6-month period this would fall out of even the most generous clinical guidelines.

We have made changes in the report to reflect the comments that HCFA made about clarifying the difference between national and local policies. We have also added additional language in the report to emphasize that during the phase-in of the DMERCs, the previous carriers were still processing claims using their own policies.

However, we believe our methodology was sound and consistent with prior OIG efforts to identify claims that appear questionable. We did not target only the largest claims for our review; we selected a statistically valid random sample of all wound care claims. In response to the organizations' concern that we used the DMERCs' proposed guidelines for our review, we used these policies because we felt the utilization standards they contained would provide us with information on the scope and nature of the problems with wound care supply claims. The supply industry had participated in the development of these guidelines and were generally supportive of them. Furthermore, there were no other non-trade association guidelines available for wound care supply utilization that were as extensive as the proposed DMERC policies. Finally, we thought this information would be useful to HCFA and the DMERCs in preparing for the implementation of the policy guidelines.

For individual claims, we assumed each type of wound supply used on a patient was medically necessary. It was the utilization of each type of wound supply that we reviewed. It is possible, as suggested by outside organizations, that what appears to be excessive utilization could be explained by the same type of dressing being used on more than one wound. However, the opposite is also the case. Various kinds of dressings could have been used on only one wound.

As we noted in this report, DMERC D reviewed a sample of billings for wound care supplies. They did determine the actual number and type of wound care supplies needed for effective treatment. Based on the findings of the medical review, they

disallowed 61 percent of the claims. In addition, the General Accounting Office found extensive overbilling in its review of wound supplies.

Our data was intended as an early warning to HCFA about the scope of potential abuse concerning wound care supplies.

APPENDIX A

WOUND CARE SUPPLY UTILIZATION GUIDELINES OCTOBER 1, 1995

HCPCS	WOUND CARE PRODUCT	STANDARD
K0196	Alginate dressing wound cover, without adhesive, 16 sq. in. or less	1/day
K0197	Alginate dressing wound cover, without adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	1/day
K0198	Alginate dressing wound cover, without adhesive, more than 48 sq. in.	1/day
K0199	Alginate dressing wound filler, per 6 inches	1/day
K0203	Composite dressing wound cover, with adhesive, 16 sq. in. or less	3/week
K0204	Composite dressing wound cover, with adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	3/week
K0205	Composite dressing wound cover, with adhesive, more than 48 sq. in.	3/week
K0206	Contact layer, 16 sq. in. or less	1/week
K0207	Contact layer, ≥ 16 sq. in. ≤ 48 sq. in.	1/week
K0208	Contact layer, more than 48 sq. in.	1/week
K0209	Foam dressing wound cover, without adhesive, 16 sq. in. or less	3/week
K0210	Foam dressing wound cover, without adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	3/week
K0211	Foam dressing wound cover, without adhesive, more than 48 sq. in.	3/week
K0212	Foam dressing wound cover, with adhesive, 16 sq. in. or less	3/week
K0213	Foam dressing wound cover, with adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	3/week
K0214	Foam dressing wound cover, with adhesive, more than 48 sq. in.	3/week
K0215	Foam dressing wound filler, per gram	1/day
K0216	Gauze non-impregnated, without adhesive, 16 sq. in. or less	3/day
K0217	Gauze non-impregnated, without adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	3/day
K0218	Gauze non-impregnated, without adhesive, more than 48 sq. in.	3/day
K0219	Gauze non-impregnated, with adhesive, 16 sq. in. or less	1/day
K0220	Gauze non-impregnated, with adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	1/day
K0221	Gauze non-impregnated, with adhesive, more than 48 sq. in.	1/day
K0222	Gauze impregnated, without adhesive, 16 sq. in. or less	1/day
K0223	Gauze impregnated, without adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	1/day
K0224	Gauze impregnated, without adhesive, more than 48 sq. in.	1/day
K0228	Gauze impregnated, without adhesive, 16 sq. in. or less	1/day
K0229	Gauze impregnated, without adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	1/day
K0230	Gauze impregnated, without adhesive, more than 48 sq. in.	1/day
K0263	Gauze elastic, all types, per linear yard	same as primary
K0264	Gauze nonelastic, per linear yard	same as primary
K0266	Gauze impregnated, any width, per linear yard	same as primary
K0234	Hydrocolloid dressing wound cover, without adhesive, 16 sq. in. or less	3/week
K0235	Hydrocolloid dressing wound cover, without adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	3/week
K0236	Hydrocolloid dressing wound cover, without adhesive, more than 48 sq. in.	3/week
K0237	Hydrocolloid dressing wound cover, with adhesive, 16 sq. in. or less	3/week
K0238	Hydrocolloid dressing wound cover, with adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	3/week
K0239	Hydrocolloid dressing wound cover, with adhesive, more than 48 sq. in.	3/week
K0240	Hydrocolloid dressing wound filler, paste, per fluid ounce	3/week
K0241	Hydrocolloid dressing wound filler, dry form, per gram	3/week

HCPCS WOUND CARE PRODUCT**STANDARD**

K0242	Hydrogel dressing wound cover, without adhesive, 16 sq. in. or less	1/day
K0243	Hydrogel dressing wound cover, without adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	1/day
K0244	Hydrogel dressing wound cover, without adhesive, more than 48 sq. in.	1/day
K0245	Hydrogel dressing wound cover, with adhesive, 16 sq. in. or less	3/week
K0246	Hydrogel dressing wound cover, with adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	3/week
K0247	Hydrogel dressing wound cover, with adhesive, more than 48 sq. in.	3/week
K0248	Hydrogel dressing wound filler, gel, per fluid ounce	3/month
K0249	Hydrogel dressing wound filler, dry form, per gram	
K0251	Specialty absorptive dressing wound cover, without adhesive, 16 sq. in. or less	1/day
K0252	Specialty absorptive dressing wound cover, without adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	1/day
K0253	Specialty absorptive dressing wound cover, without adhesive, more than 48 sq. in.	1/day
K0254	Specialty absorptive dressing wound cover, with adhesive, 16 sq. in. or less	1/every other day
K0255	Specialty absorptive dressing wound cover, with adhesive, ≥ 16 sq. in. ≤ 48 sq. in.	1/every other day
K0256	Specialty absorptive dressing wound cover, with adhesive, more than 48 sq. in.	1/every other day
K0257	Transparent film, 16 sq. in. or less, each dressing	3/week
K0258	Transparent film, ≥ 16 sq. in. ≤ 48 sq. in.	3/week
K0259	Transparent film, more than 48 sq. in.	3/week
K0154	Wound pouch, each	3/week
K0261	Wound filler, not elsewhere classified, gel/paste, per fluid ounce	1/day
K0262	Wound filler, not elsewhere classified, dry form, per gram	
A4460	Elastic bandage, per roll	1/week
K0265	Tape, all types, per 18 sq. in.	per wound cover
A4454	Tape, all types, all sizes	per wound cover

APPENDIX B

CONFIDENCE INTERVALS

We reported our projected totals by multiplying 100 by the point estimates in our samples. The point estimates represent the total allowance, number of supplies, or number of beneficiaries. The tables below include confidence interval columns. The number provided in this column is the semi-width of the confidence interval for each of the projected totals. The semi-width is the standard error of the projection multiplied by 1.96 when computing confidence intervals at the 95 percent level. The semi-width added to or subtracted from the estimated mean or total (projection) provides a 95 percent confidence interval. The table title numbers below correspond with the table numbers in the report.

Table 1. Wound Care Supply Activity: 1990 - 1994

YR	Allowances		Number of Beneficiaries		Allowance Per Beneficiary		Number of Supplies	
	Confidence Interval	Projected Total	Conf. Interval	Projected Total	Conf. Interval	Projected Total	Confidence Interval	Projected Total
1990	+/- \$4,558,237	\$53,058,000	+/- 11,000	266,400	+/- \$39	\$199	N/A	N/A
1991	+/- \$6,238,560	\$86,558,000	+/- 11,000	273,300	+/- \$56	\$317	+/- 533,474	13,325,300
1992	+/- \$2,959,330	\$49,585,000	+/- 7,000	117,300	+/- \$102	\$423	+/- 2,452,102	44,760,600
1993	+/- \$7,099,973	\$132,126,000	+/- 6,000	86,600	+/- \$275	\$1,526	+/- 3,012,140	69,123,800
1994	+/- \$5,504,363	\$97,936,300	+/- 7,000	127,300	+/- \$147	\$769	+/- 2,754,694	81,127,700

Table 3. Excessive Allowances and Units by Wound Care Product

Wound Care Product		Allowances		Number of Supplies	
		Confidence Interval	Projected Totals	Confidence Interval	Projected Total
Hydrogel Dressings	Total	+/- \$9,270,159	\$32,382,970	+/- 710,492	3,243,300
	Questionable	+/- \$7,620,692	\$24,778,466	+/- 604,321	2,389,700
	Percentage	+/- 4%	77%	+/- 4%	74%
Tape	Total	+/- \$2,495,243	\$14,324,100	Cannot Project	7,394,400
	Questionable	+/- \$1,494,300	\$9,792,200	Cannot Project	
	Percentage	Cannot Project	68%	Cannot Project	
Gauze	Total	+/- \$3,339,935	\$15,946,310	+/- 7,378,335	61,943,500
	Questionable	+/- \$181,760	\$7,772,278	+/- 4,870,170	33,032,500
	Percentage	+/- 2%	49%	+/- 2%	53%
Foam Dressings	Total	+/- \$3,866,966	\$10,513,970	+/- 295,397	1,269,400
	Questionable	+/- \$3,400,481	\$7,381,708	+/- 234,463	865,000
	Percentage	+/- 8%	70%	+/- 4%	68%
Specialty Absorptive Dressings	Total	+/- \$1,812,399	\$6,249,390	+/- 718,681	2,849,300
	Questionable	+/- \$1,432,297	\$3,963,916	+/- 559,430	1,768,200
	Percentage	+/- 6%	62%	+/- 6%	63%
Alginate Dressings	Total	+/- \$2,588,069	\$7,365,800	+/- 430,262	1,055,600
	Questionable	+/- \$1,645,784	\$2,913,323	+/- 335,241	524,600
	Percentage	+/- 12%	40%	+/- 14%	50%
Other Supplies	Total	+/- \$1,322,270	\$3,613,564	+/- 289,025	909,000
	Questionable	+/- \$1,110,985	\$2,792,247	+/- 261,352	748,600
	Percentage	+/- 18%	77%	+/- 8%	82%
Transparent Film	Total	+/- \$1,029,678	\$2,873,593	+/- 301,461	990,300
	Questionable	+/- \$909,948	\$2,297,968	+/- 269,994	787,400
	Percentage	+/- 4%	80%	+/- 4%	80%
Hydrocolloid Dressings	Total	+/- \$1,009,809	\$3,642,019	+/- 290,833	839,300
	Questionable	+/- \$769,118	\$1,963,598	+/- 259,028	548,800
	Percentage	+/- 8%	54%	+/- 10%	65%
Composite Dressings	Total	+/- \$413,717	\$1,043,871	+/- 138,432	364,700
	Questionable	+/- \$312,425	\$737,861	+/- 101,356	251,200
	Percentage	+/- 6%	71%	+/- 6%	69%

All Wound Care Products		Allowances		Number of Supplies	
		Confidence Interval	Projected Totals	Confidence Interval	Projected Total
Total		+/- \$18,109,615	\$98,026,991	+/- 9,200,087	80,928,100
Questioned	Tape	+/- \$1,494,300	\$9,026,991	Cannot Project	
	Non-Tape	+/- \$12,696,195	\$54,666,420	+/- 5,468,348	40,982,000

Top Four Wound Care Supplies That Exceeded Utilization Guidelines

Wound Care Supply - HCPCS	95% Confidence Interval	Projected Total
Hydrogel filler - K0248/K0148KE Hydrogel cover - K0244/K0148KD Foam dressing cover - K0209/K0151KB	+/- \$ 6,988,253	\$21,149,221
Tape - A4454/K0265	+/- \$1,494,300	\$9,792,200

Wound Care Activity - Eight States

Supply	Total Allowance		Questioned Allowance		Benes with Excessive Payments	
	Confidence Interval	Projected Total	Confidence Interval	Projected Total	Confidence Interval	Projected Total
Non-Tape - 8 States	+/- \$17,514,890	\$61,703,540	+/- \$12,418,648	\$37,017,607	+/- 3,012	31,900
Tape - 8 states	included		+/- \$705,562	\$5,142,581	+/- 3,788	17,600

Wound Care Activity - Five Operation Restore Trust States

Supply	Total Allowance		Questioned Allowance		Benes with Excessive Payments	
	Confidence Interval	Projected Total	Confidence Interval	Projected Total	Confidence Interval	Projected Total
Non-Tape - 5 States	+/- \$9,930,713	\$35,640,150	+/- \$5,686,759	\$18,552,330	+/- 2,772	26,200
Tape - 5 States	included		+/- \$1,151,600	\$3,698,300	+/- 3,731	14,374

Table 5 - Total Wound Care Supply Payments per Carrier

Carrier		Total \$		Per Beneficiary	
		Confidence Interval	Projected Total	Confidence Interval	Projected Total
DMERC A	Submitted	+/- \$3,604,816	\$59,317,320	+/- \$367	\$1,354
	Allowed	+/- \$1,617,170	\$21,385,200	+/- \$132	\$606
DMERC B	Submitted	+/- \$6,884,486	\$48,766,240	+/- \$1,132	\$1,460
	Allowed	+/- \$3,888,876	\$21,983,500	+/- \$566	\$832
DMERC C	Submitted	+/- \$5,205,336	\$80,658,330	+/- \$532	\$2,192
	Allowed	+/- \$3,034,259	\$41,420,600	+/- \$272	\$1,385
DMERC D	Submitted	+/- \$1,643,976	\$16,415,650	+/- \$190	\$689
	Allowed	+/- \$1,201,586	\$10,493,460	+/- \$176	\$628
Other Carriers	Submitted	+/- \$5,139,870	\$29,876,510	+/- \$135	\$345
	Allowed	+/- \$726,552	\$2,744,437	+/- \$78	\$183
Total	Submitted	Cannot Project	\$235,034,100	Cannot Project	\$1,047
	Allowed		\$98,027,100		\$795

Table 6 - Excessive Wound Care Supply Payments Per Carrier

Carrier		Non-Tape Supplies		Tape		Total Supplies	
		Confidence Interval	Projected Total	Confidence Interval	Projected Total	Conf Interval	Projected Total
DMERC A	Total \$	+/- \$1,268,246	\$9,993,753	+/- \$941,926	\$1,960,304	Cannot Project	\$11,954,057
	Percentage	+/- 2%	18%	+/- 10%	20%		18%
DMERC B	Total \$	+/- \$3,293,837	\$13,228,005	+/- \$1,484,235	\$2,402,453	Cannot Project	\$15,630,458
	Percentage	+/- 4%	24%	+/- 14%	25%		24%
DMERC C	Total \$	+/- \$279,252	\$2,242,717	+/- \$1,368,046	\$4,618,661	Cannot Project	\$28,861,378
	Percentage	+/- 4%	44%	+/- 14%	47%		45%
DMERC D	Total \$	+/- \$965,925	\$5,554,847	+/- \$965,925	\$5,554,847	Cannot Project	\$6,268,557
	Percentage	+/- 2%	10%	+/- 6%	7%		10%
Other Carriers	Total \$	+/- \$673,965	\$1,707,097	+/- \$673,965	\$1,707,097	Cannot Project	\$1,804,169
	Percentage	+/- 2%	3%	+/- 1%	1%		3%
Total	Total \$	Cannot Project	\$54,666,419	Cannot Project	\$16,243,362	Cannot Project	\$64,458,619
	Percentage		100%		100%		100%

APPENDIX C

AGENCY AND OUTSIDE ORGANIZATIONS' COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE SEP 27 1995

FROM Bruce C. Vladeck
Administrator

B. Vladeck

SUBJECT Office of Inspector General (OIG) Draft Reports on Questionable Medicare Payments for Wound Care Supplies" (OEI-03-94-00790)

TO June Gibbs Brown
Inspector General

We reviewed the subject report which contains information on Medicare payments for wound care supplies.

Our detailed comments on the report findings and recommendations are attached for your consideration. Thank you for the opportunity to review and comment on this report. Please contact us if you would like to discuss our comments.

Attachment

Health Care Financing Administration (HCFA) Comments on
Office of Inspector General (OIG) Draft Report
"Questionable Medicare Payments for Wound Care Supplies"
(OEI-04-94-00790)

OIG Recommendation

HCFA should target limited program integrity resources to those areas identified as most vulnerable to abuse. This could include edit screens at each Durable Medical Equipment Regional Carrier (DMERC) to track such wound care products as tape and hydrogel.

HCFA Response

We concur. HCFA has taken a number of specific actions to target program integrity resources to those areas most vulnerable to abuse. For example, HCFA requires that all Medicare carriers maximize program protection by focusing and identifying medical review efforts on areas where services being billed have significant potential to be medically unnecessary and excessive. The DMERCs direct their medical review efforts to monitor the utilization of wound care supplies. The DMERCs have developed and HCFA has reviewed a revised Regional Medical Review Policy (RMPR) for surgical dressings which is scheduled to be implemented in October 1995. With this policy, we believe the DMERCs will be better able to control the appropriate utilization and coverage of surgical dressings. In addition, HCFA has developed a legislative proposal to require bundling of skilled nursing facilities and nursing facilities services that in turn would require the bundling of payment for wound care supplies in Medicare and Medicaid payments to nursing homes. This may serve as an incentive for nursing homes to more closely monitor the use of wound care supplies.

OIG Recommendation

HCFA should continue to monitor wound care activity through 1996 to determine if the level of questionable payments continues. If questionable payments continue unabated, HCFA may need to reconsider the current wound care benefit.

HCFA Response

We concur. HCFA and the DMERCs will continue to monitor wound care activity through 1996. Although we do not believe it would be appropriate to change our national surgical dressing policy, we do agree that we should reevaluate our medical review claims processing efforts if questionable payments continue unabated. The implementation of the revised RMPR will assist the DMERCs in ensuring appropriate coverage and utilization of surgical dressings.

Technical Comments

It is important to note the difference between the national coverage and regional coverage of policies on surgical dressings. HCFA's national policy for surgical dressings was more restrictive prior to the March 1994 revision; the report appears to confuse HCFA's national coverage policy with the DMERC RMPR. Prior to March 30, 1994, section 2079 of Medicare Carriers Manual did limit surgical dressing coverage to primary dressings required as the result of a surgical procedure performed by a physician. However, the medical necessity time limits as well as the Certificate of Medical Necessity submission requirement were imposed by the DMERCs through their RMPRs.



HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION
Serving Medical Products Distributors & Home Care Companies Since 1902

September 19, 1995

June Gibbs Brown
Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Brown:

I. INTRODUCTION

The Health Industry Distributors Association (HIDA) is pleased to comment on the draft reports on wound care supplies, entitled "*Questionable Medicare Payments for Wound Care Supplies*," "*Marketing of Wound Care Supplies*," and "*Wound Care Supplies: Operation Restore Trust Data*," issued by the Office of the Inspector General (OIG). HIDA is the national trade association of home care companies and health and medical product distribution firms. Created in 1902, HIDA now represents over 900 home care companies and wholesale and retail medical product distributors with nearly 2000 locations. Pursuant to a physician prescription, HIDA members provide durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) services to Medicare beneficiaries who are being treated in their homes and to beneficiaries residing in nursing homes.

II. STATEMENTS IN RESPONSE TO DRAFT REPORTS

The following are statements we have in response to your three draft wound care reports. More detailed discussion of these points follow:

- **THE DMERCS DELAY IN DEVELOPING SURGICAL DRESSINGS MEDICAL POLICIES WITH APPROPRIATE UTILIZATION AND MEDICAL NECESSITY PARAMETERS WAS THE PRIMARY FACTOR IN CREATING AN ENVIRONMENT RIPE FOR POTENTIALLY ABUSIVE ACTIVITIES.**
- **THE REVISION OF SECTION 2079 OF THE MEDICARE CARRIERS MANUAL EXPANDING THE SURGICAL DRESSINGS BENEFIT WAS BASED ON SOUND CLINICAL DECISION MAKING. PATIENTS SHOULD NOT BE IN JEOPARDY OF LOSING A BENEFIT DUE TO THE FAILURE OF THE GOVERNMENT TO IMPLEMENT TIMELY UTILIZATION AND MEDICAL NECESSARY PARAMETERS .**

- THE OIG UNFAIRLY APPLIES DMERC DRAFT GUIDELINES WHICH WILL NOT BE IN EFFECT UNTIL OCTOBER 1, 1995 TO IDENTIFY QUESTIONABLE BILLING PRACTICES. IMPLEMENTATION OF NEW MEDICAL POLICY GUIDELINES MUST BE GIVEN A CHANCE TO TAKE EFFECT BEFORE CONCLUSIONS PERTAINING TO APPROPRIATE BILLING CAN BE REACHED.
- THE OIG SURVEY PRESENTED MISLEADING AND ONE-SIDED QUESTIONS TO NURSING HOMES AND BENEFICIARIES.
- THE OIG SHOULD SURVEY SUPPLIERS TO OBTAIN A FAIR DEPICTION OF THE MARKETPLACE BEFORE ISSUING THE FINAL REPORTS.
- THE OIG INCORRECTLY IMPLIES THAT LEGITIMATE MARKET-DRIVEN SUPPLIER SERVICES ARE INAPPROPRIATE.
- THE OIG SHOULD GIVE GREATER EMPHASIS TO ITS FINDING THAT THE PROBLEMS ARE LIMITED TO A SMALL MINORITY OF SUPPLIERS AND NURSING FACILITIES.

III. ANALYSIS OF CONCERNS

A. Survey Process And Questions

At the onset, HIDA would like to express its disappointment in the manner in which these reports were developed and presented. The OIG wound care surveys which were mailed to nursing facilities and beneficiaries were one sided and misleading. Many of the questions directed at the nursing homes and the beneficiaries are phrased "has a supplier [or supplier representative] ever" or "have you ever." These questions are leading and ambiguous and if answered "yes," would result in an unfavorable portrait of the supplier even though the practice may have occurred once in the course of ten years.

Despite these misleading and one-sided questions, the OIG still found that the problems identified were limited to a very few suppliers, concentrated in a few states, and involved a limited number of nursing facilities. The OIG concluded that almost two-thirds of "excessive" wound care payments were found in eight states and that three-quarters of "excessive" payments were made to 48 suppliers, 7 percent of the sample. The surveys clearly reflect that the vast majority of suppliers are operating their businesses in a responsible manner. This point must be emphasized in the final reports.

B. Supplier Services

We are concerned that many of the questions seem to be critical of the valuable services which suppliers provide in the normal course of business. Supplier provide critical functions which hold down or eliminate costs the nursing facility would incur including the following:

- *Billing/collection* activities required to generate patient specific product utilization information for payment of a product from payors for Medicare Part A, Part B and private
- *EDI/Bar Code Technology* to support order processing, product handling, packaging, billing and collection, and labor efficiency through time and motion study
- *Delivery/Transportation/Inventory Management* activities related to the movement of a product to the facility, within a facility (bar code, inventory management, storage) and activities required to send and receive product order information for the facility and for individual residents
- *Value-Added Services* including providing classes to nurses and clinicians for CEU credits on product availability and appropriateness for clinical objective

These services are essential benefits that customers receive, and nursing facilities expect to receive, from suppliers in the marketplace and should be recognized and acknowledged by the OIG.

In this report, there are numerous examples where the OIG has failed to acknowledge the types of necessary services which suppliers provide. For example, question #15 of the nursing home survey asks the following: "*Have supplier representatives ever helped you determine which patients in your facility qualify for Medicare reimbursement of wound care supplies?*" Roughly 32 percent of nursing facilities responded "yes". What is not stated is the fact that if the supplier is billing Medicare for the supplies, the supplier has the responsibility to know Medicare's billing requirements. The nursing facility frequently asks the supplier if a particular patient's condition meets the Medicare coverage requirements. In this instance the supplier has helped the nursing facility determine if the patient qualifies for Medicare reimbursement. This help is a positive service, not a negative one, and should be cited in your reports accordingly.

Another example occurs when the OIG implies in the report(s) that supplier access to patient charts is inappropriate. Page seven of the "*Marketing of Wound Care Supplies*" report states the following:

"Wound care suppliers have requested to review medical records in 17 percent of nursing homes. These homes report that the reason suppliers give for review records is to determine the eligibility of patients, view the physician orders, record treatment progression, and to gather supporting documentation for billing purposes."

Medicare frequently reminds suppliers that they are ultimately responsible for insuring that the supplier's claims are accurate and medically necessary. A responsible supplier would thus ask for verification that supplies billed to Medicare are indeed medically necessary and used by the patient, via access to nursing facility patient charts. It should also be noted that the new DMERC surgical dressing medical policy will require suppliers "to have a mechanism for determining the quantity of dressings that the patient is actually using and to adjust their provision of dressings accordingly."

C. The DMERC Process

The OIG should emphasize in the reports that the new DMERC process is critical to a successful Medicare program. It is easy to lose sight of the fact that the DMERCs have been fully in place only since October 1, 1993. With full time Medical Directors developing very strict physician practice guidelines defining medical necessity for medical supplies, including the development and publication of specific limits on how many units of medical supply a particular Medicare beneficiary can receive, inappropriate over-utilization has and will be curbed. This controlled DMERC environment is the best model for Medicare control of the program, particularly in comparison to nursing home cost reports.

The problem that has occurred with surgical dressings was that the DMERCs failed to act in a timely manner to implement DMERC medical policies with definitive utilization and medical necessity parameters. The lack of these definitive guidelines was the prime factor causing abusive billing practices.

The OIG correctly acknowledges in their reports that the DMERCs have developed a policy to clarify the coverage of the wound care benefit. This policy is expected to be effective October 1, 1995. While HIDA has requested delay in implementation of the policy until certain details are resolved, HIDA has long advocated that the development of consensus DMERC surgical dressings medical policies is a necessary solution to addressing potential fraud and abuse.

D. The OIG Unfairly Applied DMERC Draft Guidelines Which Are Not In Effect

What is perplexing is the fact the OIG in its *Wound Care Supplies: Operation Restore Trust* and *Questionable Medical Payments for Wound Care Supplies* reports "applied the proposed DMERC draft guidelines to these claims [claims analyzed for purposes of the reports] to identify questionable billing practices." The OIG is thus developing conclusions on what products "exceeded utilization guidelines" based on a policy that wasn't in effect during the time period studied (June 1994 through February 1995). Further, we question the OIG's assumption that one type of wound cover equals one wound site. A patient with multiple wounds could, and many times does, use the same type of wound cover for treating more than one wound. This assumption by the OIG led to an overstatement of how many wound care products were unnecessary since it didn't account for the fact the product could be used for more than one wound.

HIDA urges the OIG to allow the new DMERC surgical dressing guidelines to be given a chance to take effect before reaching any definitive conclusions. The product utilization guidelines combined with the billing modifiers, which identify the number of wounds on which a particular product is being used, should create future data which can be meaningfully analyzed. The draft OIG reports do not provide accurate data because they were based on a policy not implemented.

IV. HIDA RECOMMENDATIONS

HIDA is interested in working with the DMERCs, HCFA, the OIG, nursing homes, beneficiaries and others to ensure that the surgical dressings benefit provides necessary care to beneficiaries without any Medicare fraudulent abusive practices. In addition to revising its final report to address the concerns raised in this statement, HIDA offers the following recommendations. We are interested in meeting with you to discuss how best to implement them.

A. CMN's For Abusive Suppliers And Overutilized Items

First, we agree with the OIG's recommendation to HCFA that they "target their limited program integrity resources to those areas identified as most vulnerable to abuse." This is precisely why HIDA has strongly recommended that those suppliers placed on a list by the Secretary of Health and Human Services ("Secretary") in accordance with Section 1834(a)(15)(B)(i) and (ii) of the Social Security Act (amended by the Social Security Act Amendments of 1994) be subject to the certificate of medical necessity (CMN) physician completion requirement in Sections 1834(j)(2)(A) and 1834a(16). Section 1834(a)(15)(B) states that the "Secretary may develop and periodically update a list of suppliers of items for which payment may be made under this subsection with respect to whom (i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1862(a)(1) ["items and services...are not reasonable and necessary for the diagnosis or treatment of illness or injury"]; or (ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier."

It is imperative that HCFA and the DMERCs develop and make available to suppliers the criteria under which a supplier would be placed on this prepayment list, and the procedures suppliers would follow to appeal any such determination. Suppliers must be afforded appropriate due process before being placed on such a list.

Further, suppliers should be subject to the CMN physician completion requirement for those, if any, items which are placed on a list by the Secretary in accordance with Section 1834(a)(15)(A) of the Social Security Act. Section 1834(a)(15)(A) states that "the Secretary may develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization throughout a carrier's entire service area or a portion of such area." If, for example, it is deemed that surgical dressings have been overutilized then a medical necessity form should be required. Once again, it is imperative that HCFA and the DMERCs establish a fair process, with appropriate due process considerations, to ensure that overutilized items are determined in a fair manner.

B. Technical Review Committee To Review Data

Second, HIDA believes the OIG's recommendation to the DMERCs to "edit screens...to track such wound care products as tape and hydrogel" is an important step in eliminating any potential fraudulent and abusive activity. However, the DMERCs and HCFA can and should do more in this area. As we have stated on numerous occasions, HIDA is eager to work with the durable medical equipment regional carriers (DMERCs) and Health Care Financing Administration (HCFA) in tracking and analyzing claims processing utilization data in order to ensure the appropriate administration and interpretation of the DMERCs surgical dressings medical review policies (as well as all other medical policies). This could be accomplished if the *DMERCs and/or HCFA established a technical review committee whose primary responsibility would be to review and analyze data resulting from the surgical dressings Medicare benefit*. The committee should consist of a wide range of representatives of organizations and patients, including suppliers, clinicians, claims processors, and patients/consumers. The committee would suggest specific prepayment screens and refinements to the medical review policies based on post payment audits and other relevant information. The committee could generate regular reports which would be the basis for positive changes to the surgical dressings policy.

For example, it would be particularly helpful to analyze the number of exceptions to the utilization parameters. For example, if 80 percent of claims require additional documentation in order to appropriately exceed the utilization parameters set forth in a particular provision of the policy, it would then be legitimate to question whether that parameter is appropriate.

C. Consolidated Billing Proposal

Third, HIDA supports efforts to consolidate all billing for medical supplies into a nursing facility's Medicare Part A cost report for billing which occurs during the Medicare covered nursing facility stay. Therefore, only the nursing facility could bill for these services and supplies during the Medicare covered stay through its Part A cost report. To avoid any disruption of medically necessary supplies for the beneficiary, certain technical changes to Part A rules also need to be made. All enteral and parenteral nutrition products should be recognized as part of a nursing facility's ancillary costs, not routine costs. HIDA strongly opposes any changes to a supplier's ability to bill Part B for medical supplies furnished to Medicare beneficiaries after the first 100 day Part A stay.

V. CONCLUSION

HIDA appreciates the opportunity to comment on the OIG's draft wound care reports. Please contact myself or Stephen M. Azia, Assistant Director of Government Relations, Regulatory Affairs at (703) 549-4432 if you have any questions or comments.

Sincerely,



Cara C. Bachenheimer, Director
Government Relations

cc: George Grob, OIG
Penny Thompson, OIG
Rob Vito, OIG
Judy Berek, HCFA
S. Wayne Kay, HIDA
Craig Jeffries, HIDA



September 20, 1995

The Honorable June Gibbs Brown
Inspector General
Department of Health & Human Services
330 Independence Avenue, S.W.
Room 5246
Washington, D.C. 20201

Dear Ms. Brown:

The Health Industry Manufacturers Association (HIMA) is pleased to be asked by your office to respond to the three draft reports concerning wound care supplies. We will be limiting our comments to the two reports, "Questionable Medicare Payments for Wound Care Supplies" and "Wound Care Supplies: Operation Restore Trust Data." The Health Industry Manufacturers Association (HIMA) is a Washington, D.C.-based national trade association representing more than 700 manufacturers of medical devices, diagnostic products, and health information systems. HIMA's members manufacture more than 90 percent of the nearly \$50 billion of health care technology products purchased annually in the United States.

First and foremost, HIMA firmly believes that the decision of HCFA to expand the wound care benefit was the medically correct decision and no reduction in the current scope of the benefit should be entertained. The previous limitations applied to wound care coverage were not in the best interests of Medicare beneficiaries. At the same time, we have been on record both verbally and in written correspondence with HCFA, the DMERC medical directors and the OIG that appropriate management controls needed to be integrated in the implementation of the wound care benefit to avoid inappropriate or fraudulent practices. HIMA has repeatedly expressed concern that the failure to implement these controls contemporaneously with the expansion of the wound care benefit would lead to problems with abusive or possibly fraudulent activities.

Chronology of HIMA's Role in the Expansion of the Wound Care Benefit

Since 1992, HIMA, in collaboration with the National Pressure Ulcer Advisory Committee (NPUAP) and the Wound Ostomy Continence Nurses Society (WOCN), has worked with both HCFA and the DMERC medical directors to present proposals for updating HCPCS codes and medical coverage policies that would reflect current clinical practice and wound care technology. In fact, in March 1993, HCFA asked HIMA, NPUAP and WOCN to present a consensus

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proposal and educational seminar for the DMERC medical directors to define surgical dressing products and their clinically appropriate usage from a multi-disciplinary health care provider perspective. Even at that time, our proposal included recommendations that addressed potential fraud and abuse.¹

In 1993, the DMERC medical directors released their draft coverage policy on surgical dressings. HIMA, along with dozens of other clinical and provider associations commented on the restrictiveness of the policies.² The comments included "the two-week coverage limitation of surgical dressings was unrealistic and unsupported; the debridement criteria significantly deny appropriate and necessary treatments, the definition of surgical wounds was narrow and inappropriate and that classification and use specifications of dressings were inappropriate and limit the proper treatment of wounds."

The DMERC medical directors noted that they were prevented from making any substantive changes in the draft policies due to the restrictive nature of Section 2079 of the Medicare Carriers Manual, which they consider to be national policy. Over 30 beneficiary, clinician and industry groups met with HCFA Coverage Director Bob Wren in September 1993 to present a draft of a proposed revision to this policy. After a meeting with HCFA Administrator Bruce Vladeck and Dr. Helen Smits in December 1993, agreement was reached on a rewrite of section 2079.

Since that time, HIMA, in tandem with clinical and supplier associations, has worked with HCFA and the DMERC medical directors on the rewriting of section 2079, and the current final medical policy on surgical dressings. Furthermore, the National Coalition for Wound Care (of which HIMA is a member) gave recommendations on utilization parameters for surgical dressings to help curb fraud and abuse.³ These controls were not implemented.

In February 1995, HIMA met with HCFA and OIG staff and representatives of clinical and supplier associations to address the DMERCs' allegations of fraud and abuse in the wound care benefit.⁴ HCFA and OIG staff were reminded that, due to the delayed implementation of the final DMERC coverage policy, utilization and quality assurance standards were not in place. This lack of controls were a factor in the allegations of abuse in the industry.

Specific Comments

Any review of claims data must acknowledge the fact that the revisions of section 2079 policy created a new wound care benefit. Comparisons of data before and after the date of implementation are inherently suspect because the benefits are not comparable.

In reviewing the draft report "Questionable Medicare Payments for Wound Care Supplies," HIMA has concerns over the methodology used to chronicle the "excessive utilization evident in

all wound care products." We believe that the OIG has taken inappropriate clinical utilization parameters to review clinical practice retrospectively. We submit that to take utilization parameters from a final coverage policy that is not yet in force and apply them to those claims is totally inappropriate and can only lead to erroneous conclusions about utilization. This situation, coupled with the fact that HIMA, along with many of the clinical and supplier associations, believes that some of the utilization parameters in the final DMERC coverage policy (e.g., hydrogel) are incorrect makes for a dramatic overstatement by the OIG concerning the utilization of wound care products.

Along these lines, in reviewing Appendix C of the draft report, "Wound Care Supplies: Operation Restore Trust Data," we would like to offer the following specific points:

- In the hydrogel category, the alleged excessive overutilization was based on the new utilization parameter of three ounces in 30 days, whereas the old utilization parameter was at least once a day. This is one of the utilization parameters in the October 1995 final policy that we are in disagreement with the DMERC medical directors and have sent them comments to this effect.
- In the gauze category, we question what products were used in the K0218/A4200KD category, because to our knowledge no products exist in retail catalogs (i.e., Briggs, Suburban Ostomy) that fit this category.
- In the A4323 category, there was \$14,684 paid for saline solution, which is a non-covered item. We question why the DMERCs paid this since it was a non-covered item.

Furthermore, in regard to tape, we wish to make the following points:

- Previous medical policy, including transitional policy, reimbursed for "tape, any type, any size" on a per roll basis, without regard to utilization on wounds. In effect, a small length roll of tape, e.g., 1 x 18 inches was reimbursed at the same rate as a standard length roll of, e.g., 1.5" or 2" x 10 yards. The old and transitional policies encouraged overpayment for small rolls, but underpayment for the longer rolls and overutilization of tape. The new medical policy, with reimbursement by the "18 square inches," will greatly reduce incentives for overutilization and overpayment. This change just went into effect in June, 1995, after the OIG audit, and so none of the OIG's sample includes this important change. Our expectation is that a similar sample audit conducted in 1996 will show significant improvement in the area of excessive payment for tape.
- It is our suspicion that a large amount of excessive payment for tape came about in conjunction with the use of kits, where supplies, including tape, have been

billed separately. Since the draft language of the new medical policy has become available this summer, with its denial of coverage and payment for wound care kits, it is our feeling that kit suppliers and the biller/suppliers which they have serviced, are changing their practices. We feel that this will result in fewer situations of excessive allowances and utilization of tape for surgical dressing applications.

Finally, we would like to clarify some of the statements made in the first few pages of the report entitled, "Questionable Medicare Payments for Wound Care Supplies." On page 1, it states that "In 1994, 61% of the average allowance per beneficiary was for specialty dressings, up from 40% in 1992." We believe that this statement is misleading to the reader, since in 1992, these specialty dressings were not covered in the Medicare program. The next line states, "These specialty dressings are priced as high as \$35 for large hydrogel wound covers." Again, we take exception to this since the appropriate verb should be "reimbursed by the HCFA fee schedule" and not "priced." Furthermore, in rechecking HCFA's calculations for various codes, such as this one, we determined that the fee schedules were in many cases incorrect, due to arithmetic errors. This particular one, we estimated to be \$25.65 compared to HCFA's calculation of \$35.00.

On page 2, the draft states, "the former HCFA policy covered only primary dressings resulting from a surgical procedure for usually no more than two weeks." In reality, this DMERC policy was never in effect, and as I indicated earlier in our chronology of HIMA involvement in surgical dressing policy, there was such an outcry from the beneficiary and clinical community concerning the lack of patient care in the proposed policy, that the policy was changed. Furthermore, before DMERC consolidation occurred, local medical coverage policy determined coverage to be anywhere from two weeks to unlimited, depending on medical necessity. In fact, clinical associations (WOCN and NPUAP) have always recommended that the duration of coverage should be governed by individual medical necessity rather than predetermined limits.¹

Conclusion

As we stated in our introduction, we applaud HCFA for its decision to expand the wound care benefit. The benefit is medically sound and reflects the latest knowledge of wound care practice and technology. We do agree with the OIG and HCFA that the new guidelines set forth in the final DMERC coverage policy should provide the framework for the controls. We believe that HCFA and the OIG should give the medical policy guidelines a chance to take effect before they reach any conclusions regarding the fate of wound care coverage. This includes any recommendations regarding the bundling of wound care products. Again, since the reports are based upon a flawed analysis of data, the reports are not meaningful and should not be released. The product utilization guidelines combined with the billing modifiers which identify the number of wounds on which a particular product is being used, and the additional medical

The Honorable June Gibbs Brown
September 20, 1995
Page 5

necessity criteria outlined in the policy should create future data which can be meaningfully dissected. HIMA recommends that perhaps the OIG should reexamine the database a year after the benefit is in place to ensure the proper integrity of the benefit.

We appreciate having the opportunity to comment.

Sincerely,

A handwritten signature in cursive script that reads "Marcia Nusgart R.Ph.".

Marcia Nusgart, R.Ph.
Associate Vice President, Home Care

Enclosures

MN/bcj

Reference List

1. Recommendations on Surgical Dressing Codes, March 23, 1993, NPUAP, WOCN, HIMA to HCFA and the DMERC medical directors.
2. June 11, 1993 letter to DMERC medical directors from over two dozen provider, supplier, clinical and manufacturer associations concerning the DMERC medical coverage policy on surgical dressings.
3. NCWC proposal to DMERC medical directors on surgical dressing proposal.
4. November 21, 1994 HIMA letter to the Honorable June Gibbs Brown, to convene a meeting concerning alleged fraud and abuse in the wound care industry.



NATIONAL ASSOCIATION FOR THE SUPPORT OF LONG TERM C

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September 20, 1995

Ms. June Gibbs Brown
Inspector General
U.S. Department of Health and Human Services
330 Independence Ave., SW Room 54246
Washington, D.C. 20201

Dear General Brown:

I am writing on behalf of the members of the National Association for the Support of Long Term Care (NASL), an organization of companies dedicated to the improvement of services for the long term care patient. NASL has been very active in the development of the surgical dressing benefit through its membership in the National Coalition for Wound Care (NCWC) and its own efforts. We are pleased to have this opportunity to comment on the drafts of the three reports, "Questionable Medicare Payments For Wound Care Supplies", "Marketing of Wound Care Supplies", and "Wound Care Supplies: Operation Restore Trust Data". We are, however, troubled by the short time period given for the submission of these comments. These reports are quite detailed and a more thorough response could be offered if more time were available. This letter contains some general comments. Attached to this letter is a list of bullet points identifying the most serious analytical shortcomings we find with the reports.

In reviewing these reports, we are forced to conclude that there are serious flaws in the analytical methodology used to arrive at the report's conclusions. Several of the medical policies used to analyze the extent of questionable billing are the subject of considerable controversy in the wound care community at large. Moreover, it is consensus within the clinical community and within industry that each wound must be examined individually to determine the appropriateness of the surgical dressings used to heal the wound. The quantity of dressings necessary to heal a wound varies significantly based on a patient's healing rate. Accordingly, we believe that the general conclusions contained in the reports are seriously flawed.

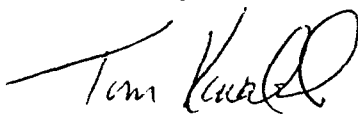
Putting aside the doubts we have about the methodology, we wish to point out that the reports raise issues concerning the surgical dressing benefit that our organization has been working with HCFA and the DMERCs to address for some time. Since the surgical dressings benefit was formally revised to reflect current clinical practice, NASL has been working with the HCFA and the DMERC medical directors to develop and issue medical policies implementing the benefit. We advocated the development of utilization parameters for the various types of dressings to be used, in order to identify those suppliers whose claims appeared to exceed the reasonable needs of the patient. We also advocated the restriction of the use of kits in the sale of surgical dressings in order to limit the excessive sale of products contained in such kits. In fact, we provided suggested language to the DMERCs for their consideration. As the reports correctly point out, the lack of clear policies had contributed to problems existing in the surgical dressing program. The overwhelmingly majority of these problems have been resolved in the past two years.

The reports appear to show that there is sufficient information available to identify a small group of suppliers whose practices are questionable. This demonstrates the efficacy of using utilization guidelines to identify outliers. It also shows that the problems identified are limited to relatively few suppliers who have commanded a significant percentage of the market geographically. More than adequate enforcement mechanisms exist to discipline these suppliers who are abusing the system. We strongly believe in such an approach to control the abuse of the program.

The revised surgical dressings benefit, which took effect March 1, 1994, was undertaken because of a clear recognition by the HCFA that a more clinically appropriate surgical dressing benefit was an important benefit of the Medicare program. In the absence of such a program, beneficiaries with serious wounds, such as Stage 4 decubitus ulcers, would be deprived of the benefits of appropriate wound healing products. While the reports concentrate on what is perceived to be a serious abuse of the system, we must not lose sight of the efficacy of the benefit in relieving the suffering of these patients and avoiding the necessity for acute care of intractable wounds.

We hope that these comments are helpful to you. If additional time is granted, we will endeavor to supply more detail than contained herein. Thank you again for this opportunity.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Kowalski", with a stylized flourish at the end.

Tom Kowalski
Executive Director

TK/kh

BULLET POINTS

“QUESTIONABLE MEDICARE PAYMENTS FOR WOUND CARE SUPPLIES”:

- The prior restrictive HCFA coverage policy was never fully implemented by the various carriers. Policy prior to 1994 as determined by the different carriers varied from the very restrictive policy described in this report to the policy of Pennsylvania Blue Shield, which allowed for coverage of a surgically debrided wound until it healed. The limit of the coverage of surgical dressings to a two week period post surgery was included in the proposed medical policies of the new DMERC medical directors and never really took effect. The rewrite of Section 2079 was the result of this destructive and overly restrictive policy.
- The dollar utilization shown in Table 1 is particularly instructive when analyzed in light of the above. The policies of the different carriers obviously led to higher utilization as shown by this table.
- Table 2 is incorrect. The policy referred to as existing prior to March of 1994 at best describes a policy that was in place for a limited number of providers depending on their carrier prior to the DMERC. Since this restrictive policy never applied to all providers, it is impossible to use it for any comparison on utilization.
- The methodology of the analysis of the surgical dressing claims is fatally flawed in several ways. One serious error is the use of the DMERC guideline for amorphous hydrogel wound filler. It is understood that this guideline is based upon an average wound size of 1 centimeter by 1 centimeter. In order to determine the proper amount of hydrogel needed to treat any given wound, it is absolutely necessary to know the size of the wound. Since this report did not examine the pertinent information on each wound analyzed, its conclusions with regard to hydrogel are of no value whatsoever. The same criticism can be applied across the board to the use of the DMERC guidelines for this analysis. The DMERCs themselves concede that the guidelines must be applied on a wound by wound basis. It is far too simplistic to analyze utilization in the manner used in the report.
- Two assumptions of the analysis must also be questioned. First, the report assumed each type of wound cover represented a separate wound site. This assumption appears to disregard the use of Primary and Secondary dressings. A second assumption, that tape is used on both Primary and Secondary dressings, is also in error.

- In choosing the claims to analyze the utilization of tape, the investigators used a methodology pre-ordained to result in overutilization. They appear to have deliberately chosen those claims for which the highest possible billings were submitted.
- The contention that excessive utilization is evident in all wound care products is clearly in error. In using the DMERC guidelines, the investigators failed to recognize the dispute that industry and the clinical community have concerning the utilization parameters for secondary dressings. While the DMERC policies would appear to limit the frequency of change of some secondary dressings to a lower limit than the primary dressing, this limit is clinically unsound. Clearly, secondary dressings must be changed when the primary dressings are changed. By applying this unsound policy, a finding of overutilization is predetermined for many secondary dressings and for many primary dressings when used as secondaries. This is the reason for the findings on page 8 that foam dressings and hydrogel wound filler are heavily overutilized. This combination of dressings is very popular among the clinical community and the use of a foam secondary is crucial in allowing the hydrogel to maximize its dwell time. The guidelines promulgated by the DMERC medical directors would result in erroneous findings both as to the hydrogel for the reasons stated earlier and as to the foam dressings which, when used as a primary, have a lower change frequency than hydrogel.
- The investigators should take no comfort in the findings of DMERC D, since the examination conducted by that DMERC was of suppliers whose conduct was already in question. No general conclusions concerning the industry as a whole can be drawn or supported by findings related to individual suppliers that have been singled out because of their prior conduct. The conclusions concerning the amount of tape used are probably inaccurate.
- During the period analyzed, the payment for tape was based on a per roll charge. The rolls most commonly used contained only three feet of tape and not ten yards. Accordingly, the analysis appears to be in error as to the amount of tape provided.
- The fact that the five Operation Restore Trust States account for a high proportion of the wound care supplies is only logical since these are the states with the largest Medicare market.
- Since the SNF or NF population is at highest risk for decubitus ulcers, it is not surprising that this population uses a disproportionate amount of the surgical dressing benefit.
- Since the revision the surgical dressing benefit (§2079), NASL has been urging DMERC medical directors to issue clear medical policies for the surgical dressing benefit. Now that this is finally and belatedly coming about, OIG has used these policies to investigate, in a look back, past practices. This is absurd. OIG's description of its retrospective confirmation of this past state of events using the

collaboratively developed criteria on highly selected data as a “report” based on a random claim sampling in the executive summary is misleading. OIG’s recommendations are infected by this error--prospective implementation of the same medical review criteria, as planned and revised where appropriate, is the right solution.

“MARKETING OF WOUND CARE SUPPLIES”

- NASL objected to the wording of the questionnaire from which this data was taken. At that time, we pointed out that the wording of the questionnaire seemed to be biased and unlikely to develop meaningful data.
- Overall, we feel that the results of this survey show that the majority of suppliers and facilities act responsibly and avoid abuses.

“WOUND CARE SUPPLIES: OPERATION RESTORE TRUST DATA”

- This report seems to simply take the conclusions of the “Questionable Payments” report and rehash them for the Operation Restore Trust states. All of the points made above for that report apply to this one.